

90-DAY RESPONSE

DCI Number: GDCI-129058-1723

Data Call-In Information

Company Name	BAKER PETROLITE, LLC
Company Address	12645 WEST AIRPORT BLVD. SUGAR LAND, TX 77478
DCI Type	Generic
Issued Date	12/12/2018
90 Day Response Deadline	03/22/2019
CRM Information	opp_ad_reevaluation_DCI_team@epa.gov
Chemical Name	Tetrakis(hydroxymethyl)phosphonium sulphate (THPS)
Chemical Number	129058

90-Day Response Information

Tracking Number	CDX_DCI_2019_000085
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DCI Level Documents

File Name	File Type	MRID	CBI	Submitted Date
Response to Generic DCI for THPS-signed.pdf	Submission Cover Letter	NA	N	03/01/2019

EPA Product Registration Number(s)

10707 60	I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.
Source EPA Registration Number(s)	
10707 57	I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.
Source EPA Registration Number(s)	
10707 59	I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.
Source EPA Registration Number(s)	
10707 66	I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.
Source EPA Registration Number(s)	

Guideline Requirement Number(s)

Guideline Requirement Number - 835.1110

Study Title	Activated sludge sorption isotherm
Protocol	N
Target Submission Date	12/12/2019
Use Pattern	X; Y
Test Substance	TGAI or PAIRA
Time Frame	12 month(s)
Footnote(s)	6. The following use sites trigger the data requirement: industrial processes and water systems. 13. EPA has published a final guideline under guideline 835.1110: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0152-0003 . If the ASSI study does not demonstrate a strong potential to sorb during activated sludge treatment, the Agency may require verification of results from the ready biodegradability study or an appropriate wastewater treatment plant (WWTP) biodegradability study as determined by the results of the ASRI test.
Registrant Response	NA

Product ingredient source information may be entitled to confidential treatment

Guideline Requirement Number - 835.1230	
Study T t e	Sediment and soil absorption/desorption for parent and degradates
Protoco	N
Target Subm ss on Date	12/12/2019
Use Pattern	X; Y
Test Substance	TGAI or PAIRA
T me Frame	12 month(s)
Footnote(s)	6. The following use sites trigger the data requirement: industrial processes and water systems.
Reg strant Response	N.A.
Guideline Requirement Number - 835.1240	
Study T t e	Soil column leaching
Protoco	N
Target Subm ss on Date	12/12/2019
Use Pattern	X; Y
Test Substance	TGAI or PAIRA
T me Frame	12 month(s)
Footnote(s)	6. The following use sites trigger the data requirement: industrial processes and water systems.
Reg strant Response	N.A.
Guideline Requirement Number - 835.2240	
Study T t e	Direct photolysis rate of parent and degradates in water
Protoco	N
Target Subm ss on Date	12/12/2019
Use Pattern	X; Y
Test Substance	TGAI or PAIRA
T me Frame	12 month(s)
Footnote(s)	6. The following use sites trigger the data requirement: industrial processes and water systems.
Reg strant Response	N.A.
Guideline Requirement Number - 835.3110	
Study T t e	Ready biodegradability
Protoco	N
Target Subm ss on Date	12/12/2019
Use Pattern	X; Y
Test Substance	TGAI
T me Frame	12 month(s)
Footnote(s)	6. The following use sites trigger the data requirement: industrial processes and water systems. 17. EPA has a published final guideline for this study 835.3110: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0152-0017 . The biodegradation study required is based on results of an Activated Sludge Respiration Inhibition test.
Reg strant Response	N.A.
Guideline Requirement Number - 835.3220	
Study T t e	Porous pot test
Protoco	N

Target Submission Date	12/12/2019
Use Pattern	X; Y
Test Substance	TGA1
Time Frame	12 month(s)
Footnote(s)	6. The following use sites trigger the data requirement: industrial processes and water systems. 16. EPA has a published final guideline for this study: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0152-0024 . The biodegradation study required is based on results of an Activated Sludge Respiration Inhibition test.
Registrant Response	N.A.
Guideline Requirement Number - 835.3240	
Study Type	Simulation Test-Aerobic Sewage Treatment-Activated Sludge
Protocol	N
Target Submission Date	12/12/2019
Use Pattern	X; Y
Test Substance	TGA1
Time Frame	12 month(s)
Footnote(s)	6. The following use sites trigger the data requirement: industrial processes and water systems. 15. EPA has a published final guideline for this study: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0152-0034 . The biodegradation study required is based on results of an Activated Sludge Respiration Inhibition test.
Registrant Response	N.A.
Guideline Requirement Number - 835.3280	
Study Type	Simulation Tests to Assess the Biodegradability of Chemicals
Protocol	N
Target Submission Date	12/12/2019
Use Pattern	X; Y
Test Substance	TGA1
Time Frame	12 month(s)
Footnote(s)	6. The following use sites trigger the data requirement: industrial processes and water systems. 14. EPA has a published final guideline for this study: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0152-0036 . The biodegradation study required is based on results of an Activated Sludge Respiration Inhibition test.
Registrant Response	N.A.
Guideline Requirement Number - 835.4300	
Study Type	Aerobic aquatic metabolism
Protocol	N
Target Submission Date	12/12/2020
Use Pattern	X; Y
Test Substance	TGA1 or PAIRA
Time Frame	24 month(s)
Footnote(s)	6. The following use sites trigger the data requirement: industrial processes and water systems.
Registrant Response	N.A.
Guideline Requirement Number - 835.4400	
Study Type	Anaerobic aquatic metabolism
Protocol	N
Target Submission Date	12/12/2020

Use Pattern	X; Y
Test Substance	TGAI or PAIRA
Time Frame	24 month(s)
Footnote(s)	6. The following use sites trigger the data requirement: industrial processes and water systems.
Reg strand Response	N.A.
Guideline Requirement Number - 850.1010	
Study Title	Aquatic invertebrate acute toxicity, test, freshwater daphnids
Protocol	N
Target Submission Date	12/12/2020
Use Pattern	X; Y
Test Substance	TGAI
Time Frame	24 month(s)
Footnote(s)	6. The following use sites trigger the data requirement: industrial processes and water systems.
Reg strand Response	N.A.
Guideline Requirement Number - 850.1300	
Study Title	Daphnid chronic toxicity test
Protocol	N
Target Submission Date	12/12/2019
Use Pattern	X; Y
Test Substance	TGAI
Time Frame	12 month(s)
Footnote(s)	6. The following use sites trigger the data requirement: industrial processes and water systems.
Reg strand Response	N.A.
Guideline Requirement Number - 850.1350	
Study Title	Mysid chronic toxicity test
Protocol	N
Target Submission Date	12/12/2019
Use Pattern	X; Y
Test Substance	TGAI
Time Frame	12 month(s)
Footnote(s)	6. The following use sites trigger the data requirement: industrial processes and water systems.
Reg strand Response	N.A.
Guideline Requirement Number - 850.1400	
Study Title	Fish early-life stage toxicity test
Protocol	N
Target Submission Date	12/12/2019
Use Pattern	X; Y
Test Substance	TGAI
Time Frame	12 month(s)
Footnote(s)	6. The following use sites trigger the data requirement: industrial processes and water systems.

Reg strant Response	N.A.
Guideline Requirement Number - 850.3300	
Study T t e	Modified Activated Sludge, Respiration Inhibition Test
Protoco	N
Target Subm ss on Date	12/12/2019
Use Pattern	X; Y
Test Substance	TGAi
T me Frame	12 month(s)
Footnote(s)	<p>6. The following use sites trigger the data requirement: industrial processes and water systems.</p> <p>12. EPA published draft guidance under guideline 850.6800 and has since published final guidance for this study under guideline 850.3300: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0154-0021. OECD Test Guideline 209 can also be used as guidance for this study, available online at http://www.oecd-ilibrary.org/content/book/9789264070080-en. The results of the Activated Sludge Respiration Inhibition Test (ASRI), GLN 850.3300, will determine which of the four biodegradation tests is/are required. o If the ASRI test EC50 is less than or equal to 20 mg/L, then either the (i) Biodegradation in Activated Sludge Study, GLN 835.3280 or (ii) Simulation Test - Aerobic Sewage Treatment: A. Activated Sludge Units, GLN 835.3240, or (iii) the Porous Pot Test, GLN 835.3220 is required. If the ASRI test EC50 is greater than 20 mg/L, then the registrant must conduct either: (i) Ready Biodegradability, GLN 835.3110, or (ii) a) Biodegradation in Activated Sludge, or b) Simulation Test - Aerobic Sewage Treatment: A. Activated Sludge Units, or c) the Porous Pot Test. o If the Ready Biodegradability study is conducted and passes, then no further testing is required. If, however, the antimicrobial fails the Ready Biodegradability study, then the (i) Biodegradation in Activated Sludge, or (ii) Simulation Test - Aerobic Sewage Treatment: A. Activated Sludge Units, or (iii) the Porous Pot study is required.</p>
Reg strant Response	N.A.
Guideline Requirement Number - 850.4400	
Study T t e	Aquatic Plant Toxicity Using Lemna spp
Protoco	N
Target Subm ss on Date	12/12/2019
Use Pattern	X; Y
Test Substance	TGAi or TEP
T me Frame	12 month(s)
Footnote(s)	6. The following use sites trigger the data requirement: industrial processes and water systems.
Reg strant Response	N.A.
Guideline Requirement Number - 850.4500	
Study T t e	Algal Toxicity
Protoco	N
Target Subm ss on Date	12/12/2019
Use Pattern	X; Y
Test Substance	TGAi
T me Frame	12 month(s)
Footnote(s)	<p>2. Tier II data on green algae (<i>Pseudokirchneriella subcapitata</i>, formerly <i>Selenastrum capricornutum</i>) is required. If the test substance has an EC50 of less than 1 mg/l (1 ppm), additional studies will be required on a freshwater diatom (<i>Navicula pelliculosa</i>) and marine diatom (<i>Skeletonema costatum</i>).</p> <p>6. The following use sites trigger the data requirement: industrial processes and water systems.</p> <p>11. In a Federal Register Notice dated June 27, 2012, EPA split the Public Draft OPPTS 850.5400 test guideline into two test guidelines: OCSPP 850.4500 and OCSPP 850.4550. See Final Test Guidelines; OCSPP 850 Series; Notice of Availability 77 FR 38282, June 27, 2012. https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0154-0028.</p>
Reg strant Response	N.A.
Guideline Requirement Number - 850.4550	
Study T t e	Cyanobacteria (<i>Anabaena flos-aquae</i>) Toxicity
Protoco	N

Target Submission Date	12/12/2019
Use Pattern	X; Y
Test Substance	TGAi
Time Frame	12 month(s)
Footnote(s)	1. Tier II toxicity data is required on <i>Anabaena flos-aquae</i> . 6. The following use sites trigger the data requirement: industrial processes and water systems. 11. In a Federal Register Notice dated June 27, 2012, EPA split the Public Draft OPPTS 850.5400 test guideline into two test guidelines: OCSPP 850.4500 and OCSPP 850.4550. See Final Test Guidelines; OCSPP 850 Series; Notice of Availability 77 FR 38282, June 27, 2012. https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0154-0028 .
Registrant Response	N.A.
Guideline Requirement Number - 860.1340	
Study Title	Residue analytical method
Protocol	N
Target Submission Date	12/12/2020
Use Pattern	X; Y
Test Substance	ROC
Time Frame	24 month(s)
Footnote(s)	4. The following use sites trigger the data requirement: slimicide in paper production and materials preservative in emulsions applied to food contact paper.
Registrant Response	N.A.
Guideline Requirement Number - 860.1380	
Study Title	Storage stability data
Protocol	N
Target Submission Date	12/12/2020
Use Pattern	X; Y
Test Substance	TEP or ROC
Time Frame	24 month(s)
Footnote(s)	4. The following use sites trigger the data requirement: slimicide in paper production and materials preservative in emulsions applied to food contact paper.
Registrant Response	N.A.
Guideline Requirement Number - 870.3100	
Study Title	90-Day oral toxicity in rodents
Protocol	N
Target Submission Date	12/12/2020
Use Pattern	X; Y
Test Substance	TGAi
Time Frame	24 month(s)
Footnote(s)	4. The following use sites trigger the data requirement: slimicide in paper production and materials preservative in emulsions applied to food contact paper.
Registrant Response	N.A.
Guideline Requirement Number - 870.3465	
Study Title	90-day inhalation toxicity
Protocol	N
Target Submission Date	12/12/2020

Use Pattern	X; Y
Test Substance	TGAI
Time Frame	24 month(s)
Footnote(s)	5. The following use sites trigger the data requirement: materials preservation, paints, disinfectants.
Reg strand Response	N.A.
Guideline Requirement Number - 870.5100	
Study Type	Bacterial reverse mutation test
Protocol	N
Target Submission Date	09/12/2019
Use Pattern	X; Y
Test Substance	TGAI
Time Frame	9 month(s)
Footnote(s)	4. The following use sites trigger the data requirement: slimicide in paper production and materials preservative in emulsions applied to food contact paper.
Reg strand Response	N.A.
Guideline Requirement Number - 870.5395	
Study Type	Mammalian erythrocyte micronucleus test
Protocol	N
Target Submission Date	09/12/2019
Use Pattern	X; Y
Test Substance	TGAI
Time Frame	9 month(s)
Footnote(s)	4. The following use sites trigger the data requirement: slimicide in paper production and materials preservative in emulsions applied to food contact paper.
Reg strand Response	N.A.
Guideline Requirement Number - 870.6200	
Study Type	Neurotoxicity screening battery
Protocol	Y
Target Submission Date	12/12/2020
Use Pattern	X; Y
Test Substance	TGAI
Time Frame	24 month(s)
Footnote(s)	4. The following use sites trigger the data requirement: slimicide in paper production and materials preservative in emulsions applied to food contact paper. 19. Acute (study due 12 months after receipt of DCI) and subchronic (study due 24 months after receipt of DCI) neurotoxicity studies are required. 21. A protocol must be approved by the Agency prior to the initiation of the study.
Reg strand Response	N.A.
Guideline Requirement Number - 870.7800	
Study Type	Immunotoxicity
Protocol	N
Target Submission Date	12/12/2019
Use Pattern	X; Y

Test Substance	TGAI, MP
Time Frame	12 month(s)
Footnote(s)	4. The following use sites trigger the data requirement: slimeicide in paper production and materials preservative in emulsions applied to food contact paper. 18. All 90-day subchronic studies in the rodent can be designed to simultaneously fulfill the requirements of the 90-day immunotoxicity studies by adding separate groups of animals for testing of immunotoxicity parameters.
Registant Response	NA
Guideline Requirement Number - 875.1100	
Study Title	Dermal exposure--outdoor
Protocol	Y
Target Submission Date	12/12/2020
Use Pattern	X; Y
Test Substance	TEP
Time Frame	24 month(s)
Footnote(s)	5. The following use sites trigger the data requirement: materials preservation, paints, disinfectants. 10. Results from a dermal indoor exposure study (875.1200) may satisfy this data requirement. 21. A protocol must be approved by the Agency prior to the initiation of the study.
Registant Response	NA
Guideline Requirement Number - 875.1200	
Study Title	Dermal exposure--Indoor
Protocol	Y
Target Submission Date	12/12/2020
Use Pattern	X; Y
Test Substance	TEP
Time Frame	24 month(s)
Footnote(s)	5. The following use sites trigger the data requirement: materials preservation, paints, disinfectants. 8. Results from this study may be used to fulfill the requirement for a dermal outdoor exposure study (875.1100). 21. A protocol must be approved by the Agency prior to the initiation of the study.
Registant Response	NA
Guideline Requirement Number - 875.1300	
Study Title	Inhalation exposure--outdoor
Protocol	Y
Target Submission Date	12/12/2020
Use Pattern	X; Y
Test Substance	TEP
Time Frame	24 month(s)
Footnote(s)	5. The following use sites trigger the data requirement: materials preservation, paints, disinfectants. 9. Results from an inhalation indoor exposure study (875.1400) may satisfy this data requirement. 21. A protocol must be approved by the Agency prior to the initiation of the study.
Registant Response	NA
Guideline Requirement Number - 875.1400	
Study Title	Inhalation exposure--indoor
Protocol	Y
Target Submission Date	12/12/2020
Use Pattern	X; Y

Test Substance	TEP
Time Frame	24 month(s)
Footnote(s)	5. The following use sites trigger the data requirement: materials preservation, paints, disinfectants. 7. Results from this study may be used to fulfill the requirement for an inhalation outdoor exposure study (875.1300). 21. A protocol must be approved by the Agency prior to the initiation of the study.
Registant Response	N.A.
Guideline Requirement Number - 875.1700	
Study Title	Product Use Information
Protocol	N
Target Submission Date	12/12/2019
Use Pattern	X; Y
Test Substance	TEP
Time Frame	12 month(s)
Footnote(s)	
Registant Response	N.A.
Guideline Requirement Number - 875.2500	
Study Title	Inhalation exposure
Protocol	Y
Target Submission Date	12/12/2020
Use Pattern	X; Y
Test Substance	TEP
Time Frame	24 month(s)
Footnote(s)	3. This study is needed for residential paint uses if sufficient quantities of THPS degradates such as formaldehyde are identified in a hydrolysis study. 21. A protocol must be approved by the Agency prior to the initiation of the study.
Registant Response	N.A.
Guideline Requirement Number - 875.2700	
Study Title	Product Use Information
Protocol	N
Target Submission Date	12/12/2019
Use Pattern	X; Y
Test Substance	TEP
Time Frame	12 month(s)
Footnote(s)	
Registant Response	N.A.
Guideline Requirement Number - SS-1218	
Study Title	Nature of Residue on Surfaces
Protocol	Y
Target Submission Date	12/12/2020
Use Pattern	X; Y
Test Substance	TGA or ROC
Time Frame	24 month(s)

Footnote(s)	4. The following use sites trigger the data requirement: slimicide in paper production and materials preservative in emulsions applied to food contact paper. 21. A protocol must be approved by the Agency prior to the initiation of the study.
Reg strant Response	N.A.
Guideline Requirement Number - SS-1376	
Study T t e	Migration Study- Food Transfer
Protoco	Y
Target Subm ss on Date	12/12/2020
Use Pattern	X; Y
Test Substance	ROC
T me Frame	24 month(s)
Footnote(s)	4. The following use sites trigger the data requirement: slimicide in paper production and materials preservative in emulsions applied to food contact paper. 20. A tiered approach is used to refine dietary exposure and risk estimates to assess exposure to the residues of concern. Based on the results of the nature of the residue on surfaces study, if residues of concern are identified, then the migration study will be required. 21. A protocol must be approved by the Agency prior to the initiation of the study.
Reg strant Response	N.A.
Guideline Requirement Number - SS-1380	
Study T t e	Migration studies - Residue Removal (Tier 1)
Protoco	Y
Target Subm ss on Date	12/12/2020
Use Pattern	X; Y
Test Substance	ROC
T me Frame	24 month(s)
Footnote(s)	4. The following use sites trigger the data requirement: slimicide in paper production and materials preservative in emulsions applied to food contact paper. 20. A tiered approach is used to refine dietary exposure and risk estimates to assess exposure to the residues of concern. Based on the results of the nature of the residue on surfaces study, if residues of concern are identified, then the migration study will be required. 21. A protocol must be approved by the Agency prior to the initiation of the study.
Reg strant Response	N.A.
Submitter Information	
Subm tter	Jason McDonald
Subm tted Date	03/01/2019
Add t onal Contact(s)	jason.mcdonald@bakerhughes.com; george.katsigras@bakerhughes.com
<p>I certify, under pena ty of aw that the information provided in this document is, to the best of my know edge and be ief, true, accurate, and comp ete. I am aware that there are significant pena ties for submitting fa se information, inc dng the possibi lity of fines and imprisonment for knowing v io ations.</p>	